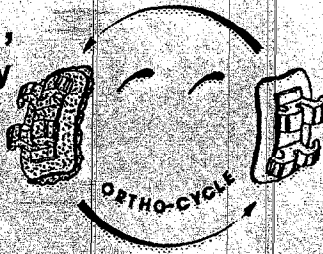


Ortho-Cycle Co., Inc.,

An ISO 9002 certified company
2026 Scott St., Hollywood,
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0196 01 JUN 12 P3 42

Food and Drug Administration, Branch HFA-305

5630 Fishers Lane Rm 1061, Rockville MD 20852

Docket no. 01N-0175

Re: Orthodontic direct bonding brackets, Class I:

Why should these be reusable ?

June 9, 2001

Gentlemen:

This company is refurbishing the above for a quarter of a century, and its president, who signs below, is well qualified in orally used materials teaching these at U. of Illinois/Chicago and South Eastern U/ Ft. Lauderdale.

There are today tens of thousands types of individual brackets on the market, varying in shape and performance. All are made of various stainless steels, often from parts which are brazed or laminated together. Made in various countries which have poorer health standards, these are supplied in non-sterilizable containers by manufacturers or retailers which sell these as SUD.

Brackets are not intrusive, but get in contact with soft tissues. None has hidden portions which cannot be inspected under magnification, and in most cases these stand well oral corrosion, decontamination/sterilization mechanical debonding (these are pulled from teeth with various pliers). After debonding, these are subjected to a treatment which has as purpose the elimination of traces of adhesive, an acrylic composite. Microorganisms cannot outlive this treatment knowing that all the carbon-carbon bonds in the polymer matrix are broken. As a result, while supplementary decontaminations are used throughout the refurbishers, these have as purpose to eliminate the effect of the recycler, and not of the bracket wearer. This is a far cry from the common reuse of never decontaminated silverware in restaurants...

From the mechanical point of view, few brackets are damaged during the treatment, and many during debonding: following this violent treatment, these which may have exhibited fatigue get visible deformations. The same happens if corrosion has taken place: both can be seen even under the naked eye, all the more under magnification (see exhibit 1 which shows brand new brackets having defects). These are caught by the recycler, who inspects these one by one, and not statistically as the manufacturers. While in hundreds of variations, all direct bonding brackets have two main parts: the size of the slot and the ability to bond of the base. The first is checked with the help of gauges, the second by visual inspection (roughness). If the slot is too small, the clinician cannot insert the arch wire which is the active part, and has to replace the bracket. If it is too wide, he has to compensate by bending the wire, process which is basic in the profession. If the base doesn't bond enough, the bracket may get debonded and in the worst case, swallowed. According to an attorney of the American Association of Orthodontists, (Exhibit 2), even this is not dangerous. The same association has declared recycled brackets to be Safe and Effective (Exhibit 3). Based upon the above, there is no reason to declare the other stainless steel devices as reusable, while direct bonding brackets not.

Sincerely, C G Matasa, DCE, DSc.

01N-0175

C 1

Revue d'Orthopédie Dento Faciale



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exhibit 1

Attaches recyclées :
doit-on considérer les attaches neuves
comme des modèles de référence ?

*Recycled brackets :
should the new ones
be considered a standard ?*

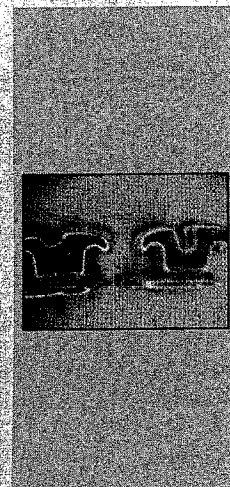
C. G. MATASA

ÉDITION  INTERNATIONALE

<http://www.sdid.org>

Attaches recyclées : doit-on considérer les attaches neuves comme des modèles de référence ?

Recycled brackets: should the new ones be considered a standard ?



Claude G. MATASA

Traduction de C.J. BOLENDER

RÉSUMÉ

Dans l'article que nous argumentons, l'apparence morphologique de la surface d'attaches sélectionnées, tant neuves que reconditionnées, a été étudiée à l'aide de la microscopie électronique à balayage. Les conclusions qui en ont été tirées étaient que les attaches recyclées, à la différence des attaches neuves, présentent des modifications sévères qui ne permettent pas leur réutilisation. Les auteurs affirment de plus que les risques juridiques encourus engendrent des problèmes financiers importants qui estompent l'intérêt des économies réalisées.

La présente étude fait remarquer qu'aussi longtemps que les attaches neuves, mises en vente de nos jours, présenteront des imperfections rendant leur utilisation impossible et mettant en danger la santé du patient, il serait malséant de demander au « recycleur » de les utiliser comme modèles de référence.

La procédure d'inspection soigneuse, une par une, des attaches recyclées, qui se situe à l'opposé de la procédure « statistique » pratiquée par les fabricants, permet au clinicien d'utiliser des attaches testées au feu et sélectionnées par des moyens supérieurs aux leurs.

En ce qui concerne l'aspect économique, recycler des attaches déjà utilisées peut diviser le coût par 10. Mais celles-ci sont au moins aussi exemptes de danger que des attaches neuves, du fait de leur double stérilisation. Nous savons d'autre part qu'en un quart de siècle, jamais aucun procès devant une cour de justice n'a prononcé une quelconque condamnation à propos d'attaches recyclées.

ABSTRACT

In that article, scanning electronic microscopy was applied to assess the surface morphological appearance of selected new and reconditioned brackets. The conclusion reached was that recycled brackets, as a difference from the new ones, present problems which do not allow for their reuse. In addition, its authors claim that the legal implications incurred raise financial problems which compensate the savings.

The present study points out that as long as the new brackets released today have flaws which endanger the health of the patient and ultimately make their use impossible, it is improper to ask the recycler to use them as a model.

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In contrast, the latter's careful one-by-one inspection, which differs from the "statistical" one practiced by manufacturers, enables the clinician to use attachments fire-tested and selected by means surpassing his own.

Concerning the economic part, not only recycling somebody's brackets may lead to savings amounting up to a 10:1 price ratio, but these are at least as safe as the new ones, being twice sterilized: in over a quarter of a century of their reuse, no suit in court was ever filled pointing these as reason.

MOTS CLES

Attaches orthodontiques - Conservation des ressources naturelles - Reutilisation de dispositifs médicaux.

KEYWORDS

Orthodontic brackets - Conservation of natural resources - Reuse of medical devices.

1 - INTRODUCTION

Les attaches à collage direct présentent de nos jours des caractéristiques complexes qui requièrent des procédés de fabrication très sophistiqués. Il en résulte que le coût de l'unité de poids des attaches métalliques peut dépasser de trois fois celui des mêmes attaches réalisées en or, alors que dans le cas des attaches céramiques, il peut s'agir de six fois. Très rapidement, après la production en masse des attaches neuves, on a procédé à la réutilisation d'attaches à collage direct selon deux procédés, qui ont déjà été proposés en 1975, à savoir celui de la Société Esmadent (Esmadent Company), procédé dans lequel la colle était carbonisée, et celui de la Société Ortho-Cycle (Ortho-Cycle Co.), où celle-ci était dissoute.

Depuis cette date, une pléthore de sociétés similaires se sont développées dans l'ensemble du monde, rendant évident l'intérêt et l'acceptation du procédé par les cliniciens. Réalisant le potentiel économique que cela représentait, les fabricants qui font partie de nos jours de l'organisation internationale qui s'oppose au recyclage (The Orthodontic Manufacturing Association, OMA) s'y étaient ralliés (Lancer Orthodontics). Certains de ceux qui avaient tenté l'aventure à ce stade précoce ont disparu (Ortho Bonding Co.) ou l'ont abandonné (Lancer Orthodontics, Esmadent, Century 2001).

La seule société qui fut de ces débuts et qui est toujours prospère de nos jours est Ortho-Cycle Co. Le prix de son succès fut élevé : elle

Today's direct bonding brackets have complex features which often require sophisticated manufacturing procedures. As a result, the cost of a weight unit of the metallic ones may well surpass three times that of the same in gold bullion, while in the case of the ceramic brackets, this ratio may be as high as six to one. The reuse of direct bonding brackets has occurred therefore quite fast after the mass production of the new ones, two processes being offered as early as 1975: that of Esmadent Company, where the adhesive was charred, and that of Ortho-Cycle, where it was dissolved. Since then, a plethora of companies have mushroomed all over the world, evidencing the clinician's interest and acceptance. Realizing the economic potential, manufacturers which are today part of an international organization opposing recycling (the Orthodontic Manufacturing Association, OMA) have stepped in (Lancer Orthodontics). Some of these, however, have tried themselves to do it, but quit (Lancer Orthodontics), as several other recyclers which didn't cope with the task (Ortho Bonding Co., Brackets Laboratories, Esmadent, Century 2001).

Ortho-Cycle Company, which started the movement using the dissolution of the adhesive with chemicals, is still thriving

fut traînée en justice par un fabricant pour contrefaçon d'une invention brevetée (1), régulièrement menacée et attaquée par l'OMA et ses partenaires, à la fois dans les journaux professionnels et à la télévision (deux émissions à huit ans d'intervalle à la NBC-TV). Les sommes consacrées à tenter de restreindre cette activité porte-drapeau des sociétés sont suffisantes pour démontrer que le recyclage des attaches a cessé depuis longtemps d'être une activité subalterne, et elle représente une entaille majeure dans les revenus des fabricants.

Dans les lignes qui suivent, et en contradiction avec l'article cité, nous démontrerons que les attaches recyclées se présentent comme une solution fiable par rapport aux attaches neuves. Ainsi que l'a affirmé dans son rapport de 1997-1998³³, le président de l'American Association of Orthodontists, les attaches recyclées sont à la fois «sans danger et efficaces». De plus, nous montrerons que les marques d'attaches neuves actuelles ne peuvent pas représenter un modèle absolu et que l'action des «recycleurs ne se limite pas seulement à sélectionner, mais encore améliore la qualité des attaches. Alors que des attaches recyclées n'ont jamais fait l'objet d'un procès en justice, les marques d'attaches neuves l'ont fait à plusieurs reprises⁸».

Dans l'article que nous critiquons, un parallèle a été établi entre attaches neuves et attaches recyclées, en prenant comme modèles de référence deux types d'attaches (Mini Diamond d'Ormco et Master Series de American Orthodontics) : de ce fait, nous nous limiterons à l'examen de ces deux types d'attaches.

today. The price of its success was high, as it was sued by a manufacturer for... patent infringement, repeatedly threatened and attacked by OMA and its partners both in the professional journals and the television (two broadcasts, eight years apart, by NBC-TV). Just by adding the amounts spent to curb this company's flag-bearing activity it is enough to demonstrate that bracket recycling has ceased since long to be menial, representing today a major dent in the manufacturer's revenues.

In what follows, in contrast with the article we are responding to, we will document that recycled brackets present a viable alternative to the new ones, being, as the President of the American Association of Orthodontics himself has stated in his 1997-1998 report³³, both "safe and effective". In addition, we will show that the brand new brackets of today cannot constitute a standard to be followed and that the recycler's action may actually not only select, but also improve the quality of the attachments. While recycled brackets have not ever been the object of a suit in court, brand new ones were⁸.

In the preceding article, a parallel new vs. recycled was performed by taking two lines of brackets as standard (Ormco's Mini Diamond and American Orthodontics' Master Series) without following the same brackets before and after their individual exposure to bonding and recycling: in what follows we will restrict our examination only to these two brands.

2 - REVUE DE LA LITTÉRATURE

2 - LITERATURE REVIEW

Comme toutes les informations qui suivent manquent dans l'article que nous argumentons, il nous a semblé nécessaire de compléter l'image du champ couvert.

Pour éviter des problèmes de crédibilité, aucune des références données n'est basée sur des études personnelles.

2 - 1 - Risques sanitaires

En France les attaches métalliques à collage direct sont classées en classe IIa, alors qu'aux États-Unis elles le sont en classe I, c'est-à-dire

As all the following information were missing in the article to which we are responding, we felt necessary to complete the image of the field covered. To avoid credibility problems, none of the references quoted in this part is based upon our own studies.

2 - 1 - Health hazards

In France, metallic direct bonding brackets are classified as Class IIa, while in the US Class I, i.e. posing the lowest potential

la catégorie qui correspond en matière de santé au danger potentiel le plus bas. D'après Salley Bowers³, «attorney» pour l'American Association of Orthodontists, «même si une attache venait à se détacher et que le patient l'avale, il n'en résulterait aucun dommage pour celui-ci».

D'autres problèmes ont été ignorés alors que l'on prêtait beaucoup d'attention à la décontamination des attaches réutilisées, en un temps où des dispositifs invasifs comportant des parties plastiques difficiles à nettoyer et à stériliser, du genre «pace-maker», ballons et cathéters d'angioplastie étaient réutilisés couramment dans les hôpitaux de pointe. On peut se demander pourquoi la possibilité de stérilisation des attaches métalliques et céramiques a été remise en question et non pas le besoin de décontamination des attaches neuves, alors que ces dernières sont assemblées de manière industrielle par des ouvriers vivant dans des pays dont les habitudes sanitaires sont précaires ?

Le processus de rupture des liens chimiques d'une colle amène également la destruction de tout micro-organisme, alors que les plateaux de rangement plastiques, les flacons etc., dans lesquels les marques d'attaches neuves sont expédiées, démontrent que ceux-ci ne sont jamais décontaminés. A l'inverse, les attaches recyclées par nos soins et soumises comme à l'habitude à une décontamination, juste avant leur expédition (sans contact avec nos techniciens), ont été trouvées parfaitement stériles par un laboratoire clinique auquel elles avaient été adressées²⁸. Autrement dit, alors que nous sommes seulement censés les décontaminer, nous avons dépassé la demande.

Comment ceci tient-il la comparaison avec un repas pris dans un restaurant avec des couverts en argent qui n'auront été lavés que grossièrement après leur usage précédent ? Pourquoi affirmer qu'une fois utilisées, les attaches peuvent être dangereuses du fait qu'elles libèrent des métaux lourds et prétendre que pendant leur usage normal ces couverts n'en libèrent aucun ?

Si une attache est susceptible de se corroder alors qu'elle est neuve, il est certain qu'elle gardera sa susceptibilité à la corrosion, bien qu'elle ait bénéficié d'une chance d'élimination de la partie corrodée par le recycleur, qui pourra en observer aisément les signes révélateurs caractéristiques. Il est intéressant de noter que, bien que les matériaux de base soient des aciers inoxydables et des matériaux de soudure, certaines attaches, toujours utilisées de nos jours, sont connues pour être sus-

danger as health concerns. According to Sally Bowers, attorney for the American Association of Orthodontics, "even if a bracket could become detached and the patient could swallow it, this will not result in an injury to the patient"³.

While a lot of attention has been given to the decontamination of reused brackets in a time when invasive devices containing difficult to clean and sterilize plastic parts such as pacemakers, angioplasty balloons and catheters are currently reused in top ranking hospitals, other issues have been ignored. Why the ability to sterilize used metal and ceramic attachments was often questioned, and not the need for decontaminating the new ones? (Most of these are tediously assembled by workers living in countries where the health standards are poor).

In the case of any recycling, the process of breaking the chemical bonds in an adhesive will for sure lead also to the killing of any micro-organism. In contrast, the plastic organizers, vials, etc. in which the brand new ones are shipped demonstrate that these were not decontaminated by heat or steam. In contrast, brackets recycled by us, which were subjected as usual to a final decontamination just prior to their shipping (against a contact with our technicians), have been found by the addressee, a clinical laboratory, to be sterile²⁸. In other words, while we only suppose to decontaminate them, we have exceeded the demands.

How this compares with eating in a restaurant with silver ware which has been barely washed from their previous use ?

Why claim that once used, the brackets may be dangerous due to the heavy metals released, and pretend that while in normal use, the same did not leach any? If an attachment was corrosion susceptible when new, for sure it has remained so. As it will be shown below, corroded attachments are actually offered by the recycler a chance to be detected due to their characteristic tell-tale signs. In contrast, some of the brackets

ceptibles de corrosion, comme l'atteste l'exclusion en Allemagne des soi-disant «aciers automatiques», en tant qu'alliages dentaires⁴. La dissolution de l'adhésif ou l'électro-polissage de l'acier peuvent-ils modifier la composition du métal, par opposition à l'action du soufre, qui est intentionnellement ajouté à l'alliage pour économiser de l'énergie, comme on le fait pour des lames ? Il est intéressant de noter que ce ne sont pas seulement les matériaux utilisés qui peuvent être nocifs, mais également la façon de les assembler ainsi que l'interaction qui en résulte, comme nous le verrons ultérieurement.

2 - 2 - Aspects juridiques

À la différence de la réutilisation de la plupart des dispositifs médicaux, celle des attaches à collage direct est exempte à la fois d'exigences de notification avant mise sur le marché et de l'autorisation de la Food and Drug Administration (FDA, organisation de contrôle sanitaire) dans la mesure où les «Good Manufacturing Practices» (GMP : pratiques de bonne fabrication) sont suivies³⁹. Une fois de plus, dépassant la demande, la société Ortho-Cycle Co. s'est mise en conformité avec ces pratiques⁹ dès 1991. Ainsi la Food and Drug Administration (Office américain chargé du contrôle pharmaceutique et alimentaire) a trouvé pour nos attaches «une équivalence fondamentale avec les dispositifs utilisés comme modèles de référence et légalement mis sur le marché, permettant ainsi à ces attaches d'accéder au dit marché».

En Floride, un recycleur doit se conformer aux mêmes exigences que celles qui pèsent sur le fabricant, et notre «licence» précise que nous sommes réellement des «fabricants de dispositifs»³⁸. De nos jours, Ortho-Cycle est proche de l'obtention de la certification ISO 9002, étant engagée dans le processus d'obtention de la marque CE y afférente. Il est intéressant de noter que la traçabilité des attaches recyclées est toujours réelle, par le fait que dans tous les processus de remise à neuf, par exemple par carbonisation ou par dissolution, les marques disto-gingivales peintes disparaissent, permettant de les distinguer ainsi aisément des attaches neuves.

Un autre fait important est que tous les fabricants inscrivent sans discrimination sur toutes leurs attaches, la mention : «à usage unique». Cette affirmation récente est en opposition avec de vieilles pratiques, comme on peut s'en rendre compte en

which are still used today are known to be corrosion susceptible, as witnessed by the exclusion of the so called automatic steels for dental alloys in Germany⁴. Could the dissolution of the adhesive, or the seldom performed flash electro-polishing of the buccal side of the bracket, as performed at Ortho-Cycle, modify the metal's composition, in contrast with what some manufacturers are doing by willingly adding sulfur into the alloy to save energy and cutting blades ?

2 - 2 - Legal aspects

As a difference from the reuse of most medical devices, that of the direct bonding brackets is exempt from both a premarket notification requirement and an FDA clearance as long as the Good Manufacturing Practices (GMP) are followed³⁹. Again exceeding demands, Ortho-Cycle Co. has fulfilled these as early as 1991⁹. Thus, the Food and Drug Administration has found for our brackets "a substantial equivalence to the legally marketed predicated devices, permitting these devices to proceed to the market".

In Florida, a reprocessor has to comply with the same requirements as a manufacturer, and our license actually states that we are device manufacturers³⁸. In our days, Ortho-Cycle is soon due to have soon the ISO 9002 certification, while being in the process to get the afferent CE mark. According to the latter certification, it is interesting to note that recycled brackets are traceable by the fact that in either of the refurbishing processes, i.e. charring or dissolution, the painted disto-gingival marks are removed, making them easily distinguishable from the new ones.

Another important issue is the fact that almost all the manufacturers are labelling indiscriminately their attachments "for single use only". This recent claim is contrary to old practices, as one may see reading John Joseph Ravenscroft Patrick, the originator of an appliance which presented "nearly all

lisant John Joseph Ravenscroft Patrick, l'initiateur d'un appareil qui présente «à peu près toutes les caractéristiques valables que doivent posséder des arcs d'expansion»⁴¹. En effet à en croire Patrick, cet arc «peut être utilisé successivement dans de nombreux cas»³¹. Notant cet abus, la Food and Drug Administration a exigé des fabricants de documenter de telles plaintes, les mettant dans cette position embarrassante d'avoir à montrer ce qu'ils reprochent aux attaches recyclées¹¹.

2 - 3 - Soutien des cliniciens

Certains des problèmes évoqués plus haut ont été discutés dans l'*American Journal of Orthodontics* pendant des années ; nous en extrayons l'opinion exprimée par différents cliniciens.

Ainsi, un des commentaires précise que ce n'est pas le fait de mentionner sur un produit : «à usage unique», qui le rend à usage unique. En portant cette mention sur les pinces orthodontiques, il en résulterait un tollé dans le domaine des ventes, et ce serait également mensonger³⁵. Dans une autre étude traitant de ce sujet, l'auteur conclut que : «pour le clinicien moyen, l'usage répété d'appareils délicats démontre qu'avec un reconditionnement correct, il est possible non seulement d'effectuer un traitement, mais même d'atteindre des performances similaires à celles obtenues avec des attaches neuves»⁶. Dans une autre étude encore, l'auteur montre que le recyclage pouvait être d'une grande aide pour la profession, à la fois du point de vue économique et du point de vue écologique, aussi longtemps que l'orthodontiste est conscient des méthodes variées intervenant dans ce domaine⁵. Consulté, un autre clinicien, qui est également un expert mandaté par l'*American Journal of Orthodontics*, a conclu : «à partir du moment où l'intégrité et les caractéristiques techniques de l'appareil ont été maintenues et l'appareil stérilisé, la réutilisation d'attaches orthodontiques peut faire partie de la pratique orthodontique»¹⁸.

Les lecteurs du *Journal of Clinical Orthodontics* ont également apporté un grand soutien : «Le recyclage produit une attache impossible à distinguer d'une attache neuve»⁴⁰, «Le recyclage permet une réduction des coûts»¹², «Des méthodes éprouvées pour le recyclage d'attaches collées diminueront encore les frais»⁴⁴, «Si, sous des grossissements

the valuable features which are to be found in expansion arches»⁴¹. Indeed, according to Patrick, his arch could "be used in many successive cases"³¹. Noticing the abuse, the Food and Drug Administration has required the manufacturers to document such claims, putting them in the embarrassing position to show what is wrong with their brackets¹¹.

2 - 3 - Clinician's support

Some of the above issues have been discussed in the *American Journal of Orthodontics* during the years, from which we will present the opinion of several clinicians.

Thus, one of the comments shows that "Labelling a product 'single use only' does not make it so. Labelling orthodontic pliers 'single use only' would be a great boost for sales, but it would be similarly untruthful"³⁵. In another study dedicated to the topic, the author concluded that "for the average clinician, the repeated use of delicate appliances demonstrates that with proper reconditioning, it is possible not only to save, but also to achieve a performance similar to that of the new brackets"⁶. In yet another study, the author showed that recycling "can be of great aid to the profession, both economically and ecologically, as long as the orthodontist is aware of the various methods involved in this field"⁵. Consulted, another clinician who is also an attorney, a judge and a legal consultant for the *American Journal of Orthodontics* has concluded "Provided that the integrity and specifications of the appliance have been maintained and the appliance has been sterilized, the reuse of orthodontic brackets can be incorporated in orthodontic offices"¹⁸.

The readers of the *Journal of Clinical Orthodontics* have been equally supportive : "Recycling produces a bracket indistinguishable from a new one"⁴⁰; "Recycling permits cost reduction"¹²; "Improved methods for recycling of bonded brackets will cut the costs further"⁴⁴; "If, under strong magnification, the brac-

importants, la gorge de l'attache apparaît non distordue et la base de l'attache avec sa grille en bonne forme, je ne vois pas de raison pour ne pas l'utiliser au moins une fois de plus»³², «La place occupée par le recyclage dans votre cabinet peut être plus importante que vous ne le pensez»¹⁴.

ket slot appears undistorted, and the bracket base and mesh are still in good shape, I see no reason not to use them at least once more time»³²; "Recycling space within your office may have more possibilities than you would think"¹⁴.

3 - PROPRIÉTÉS

3 - PROPERTIES

3 - 1 - Force d'adhésion

Dans certaines circonstances, on a pu trouver les propriétés des attaches recyclées amoindries par rapport à celles des attaches neuves, comme cela est relaté dans l'article que nous critiquons. C'est le cas lorsqu'il est fait appel au procédé thermique⁴². Dans d'autres études tout au contraire, elles furent trouvées identiques en qualité, voire meilleures. Ainsi une étude effectuée avec l'aide du National Institute of Standards and Technology (Gaithersburg, M.D.) a trouvé des attaches recyclées dotées d'une force de résistance au cisaillement comparable à celle des attaches neuves⁷. Une thèse largement utilisée par l'OMA (The Orthodontic Manufacturing Association) pour discréditer le recyclage, thèse réellement et volontairement dénaturée dans sa présentation, a montré : «quoiqu'une différence statistique en matière de force d'adhésion soit apparue entre la plupart des groupes d'attaches, il n'est pas évident qu'il existe une différence cliniquement significative... C'est pourquoi la question d'importance clinique reste sans réponse... Les attaches recyclées par la société X (X = Ortho-Cycle) présentent une force d'adhésion significativement plus importante comparativement aux attaches neuves ou collées-recyclées»¹⁰, «Des attaches recyclées par Ortho-Cycle Co., collées avec l'adhésif Heliosit, ont montré une force d'adhésion de 20 % supérieure à celles des attaches neuves⁴³, même avant d'avoir été traitées pour augmenter leur force d'adhésion», «Des attaches mordancées, coulées et garnies de grille de rétention, ont montré, quelle que soit la méthode de recyclage utilisée, des forces de fracture qui ne sont pas significativement plus faibles que celles rencontrées dans le collage d'attaches neuves non encore utilisées... En augmentant la rétention mécanique à travers un procédé de mordantage, le collage par adhésif à des attaches reconditionnées peut être rendu aussi robuste que celui effectué avec des attaches neuves»³⁶, «La silanation, et la silanation accompagnée de traitements de mordantage augmentent de façon significative la force

3 - 1 - Bond strength

While in some instances recycled brackets have been found to have lesser properties than the new ones, as quoted in the article we are responding to, and as found to be the case with the thermal process⁴², in other studies these were found to be the same or even better. Thus, a study performed with the help of the National Institute of Standards and Technology (Gaithersburg, MD) has found some of the recycled brackets to have a shear bond strength comparable to the new ones⁷. A thesis widely used to discredit recycling by OMA, which was actually been willingly misrepresented, showed: "Although a statistical difference for shear bond strength was found between most of the bracket groups, it is not known if a clinically significant difference exists... therefore the question of clinical significance still remains unanswered... The company X recycled brackets (X= Ortho-Cycle, our note) had a significantly greater bond strength than the new or bonded-recycled brackets"¹⁰. Brackets recycled by Ortho-Cycle Co. bonded with the adhesive Heliosit were found to exhibit a bond strength 20 % higher than the new ones⁴³, even before being treated for enhanced bond strength: "Etched, cast and mesh-backed brackets, regardless of reconditioning method, yielded fracture strengths not significantly less than those of bonds to new, unused brackets... By increasing mechanical retention through an etching procedure, adhesive bonds to reconditioned brackets can be rendered as strong as those to new brackets"³⁶. "Silanation and silanation plus etching treatments significantly increased bond strength of base

d'adhésion de la grille de la base, le traitement par silanation arborant la plus grande valeur... Le mordantage, le mordantage plus la silanation, le mordantage plus l'activation de surface, augmentent la force d'adhésion du Dynalock, le mordantage arborant ici sa plus grande valeur. La silanation et le mordantage sont effectués commercialement (Ortho-Cycle Co.)»³⁷.

3 - 2 - Dimensions de la gorge

Sauf si elles sont soumises à un électropolissage abusif comme celui nécessité après un reconditionnement thermique (sinon les attaches restent colorées en noir intense) les gorges des attaches ne devraient pas être affectées. En comparant des gorges : «après deux recyclages successifs, il ne fut détecté aucune modification cliniquement significative au niveau de l'ajustage de l'arc dans l'attache»¹⁶. Dans la thèse de l'Université d'Iowa précédemment citée comme étant utilisée par l'OMA (Orthodontic Manufacturing Association), il est précisé que : «les résultats indiquent également, qu'à l'exception des groupes d'attaches recyclées par les sociétés X et Z, il n'y avait pas de différences significatives dans les groupes de dimensions des gorges... La différence est inférieure à 0,0005 inch, ce qui est cliniquement insignifiant»¹⁰. Il est intéressant de noter que cette thèse, maintenant connue, a trouvé une dimension moyenne des gorges des attaches neuves de 0,0187 au lieu de 0,0180 inch, en opposition flagrante avec la déclaration des fabricants disant : «que la variation dans les dimensions des gorges, pour différents fabricants, s'échelonnait entre 0,0000 et 0,0002 inch»³⁰. Une étude, effectuée par le même expert, qui fut appelé à témoigner en cour de justice dans l'affaire D.M. Fox contre T.P. Orthodontics, montra que : «les attaches neuves ont révélé un écart des dimensions des gorges (base) de 0,0028 inch. De ceci nous concluons que les modifications induites par le recyclage sont considérablement moindres que les variations autorisées dans la fabrication des attaches neuves... Le relevé des mensurations a été effectué à l'aide d'un «Smart Scope» fabriqué par la Optical Gauging Products Corporation»¹³.

3 - 3 - Propriétés mécaniques et chimiques

Des attaches recyclées ont été testées et comparées avec des attaches neuves. Voici quelques conclusions : «La plupart des attaches orthodon-

mesh, with silanation treatment having the greater value... Etching, etching plus silanation and etching plus surface activation increased the bond strength of based Dynalock, with etching having the greatest value. Silanation and etching were done commercially (Ortho-Cycle Co.)»³⁷.

3 - 2 - Slot dimensions

Unless subjected to an abusive electro-polishing, such as the one needed after thermal reconditioning (otherwise the brackets will be dark colored), the slot size should not be affected. Comparing slots after "two successive recycles, no clinically significant changes in the fit of the wire to engage the bracket were found"¹⁶. In the Iowa University thesis mentioned before as being used by OMA it is shown : "The results also indicated that, except for company X and Z recycled groups, there was no significant differences in group slot sizes... the difference is on the magnitude of less than .0005 inches, which is clinically insignificant"¹⁰. Interestingly, this now famous thesis found a mean slot size for a brand new bracket to be .0187 instead of .0180, in sharp opposition with manufacturers' claim that "the variation in the slot size for different manufacturers ranged between .0000 and .0002"³⁰. A study performed by the same expert who was called to testify in court in the case D.M. Fox against TP Orthodontics showed the following: "The new brackets exhibited a range of slot widths (bottom) of .0028 inches. From this I conclude that the changes induced by recycling were dramatically less than the variability allowed in the manufacture of the new brackets. The slot measurements was performed were taken utilizing a 'Smart Scope' manufactured by Optical Gauging Products Corp."¹³.

3 - 3 - Mechanical and chemical properties

Recycled brackets have been tested and compared with the new ones. Here are some conclusions : Most orthodontic

tiques sont réalisées en acier inoxydable austénitique. Si cet acier est chauffé à une température comprise entre 400 et 900° C, on observe un précipité de carbure de chrome, dont il résulte une désintégration partielle de l'alliage menant à un affaiblissement structurel général... Il est intéressant de noter que le procédé de la société Esmadent se situe dans la catégorie où l'on observe une précipitation de carbure aboutissant à une diminution de la résistance à la corrosion... Le procédé de la société Ortho-Cycle n'altère pas les propriétés mécaniques du métal de l'attache et serait considéré comme la méthode la plus souhaitable... Le procédé de cette société ne provoque pas de changement dans les propriétés mécaniques de l'attache. La dureté, la force d'adhésion théorique et la microstructure restent inchangées par rapport à un groupe de contrôle»⁵.

«Les attaches n'étant manifestement pas exposées à des températures élevées et étant soumises dans le même temps à un processus de passivation (procédé Ortho-Cycle), aucun des appareils contrôlés n'a montré de signes de corrosion ou amené des décolorations de l'émail, en dépit du fait que les bases utilisées dans cette étude ont été réellement rendues rugueuses au moyen d'une corrosion contrôlée»⁶.

«Le recyclage d'attaches, soit par méthode chimique, soit par traitement thermique, ne laisse pas apparaître de différences significatives au niveau du potentiel de corrosion lorsque l'on compare ces attaches à d'autres, non traitées»¹⁵.

brackets are made of austenitic stainless steel. If this steel is heated to between 400 and 900° C, a chromium carbide precipitate is formed and as a result, a partial disintegration of the alloy results, leading to a general structural weakening... It is interesting to note that company E's process (Esmadent, our note) falls in the range of carbide precipitation leading to a decrease in corrosion resistance... The company O-C method (Ortho-Cycle, our note) did not alter the mechanical properties of the bracket metal and would be considered the most desirable method... The Company O-C process did not cause a change in the mechanical properties of the bracket. The hardness, theoretical tensile strength and microstructure remained the same as the control»⁵.

“Not being obviously exposed to higher temperatures and being subjected at the same time to a process of passivation (Ortho-Cycle's process, our note), none of the appliances checked has shown signs of corrosion or led to enamel staining in spite of the fact that the bases used in this study have been actually roughened through a controlled corrosion”⁶.

“Bracket recycling, by either chemical or heat treatment methods, when compared to untreated brackets, shows no significant difference in corrosion potential”¹⁵.

4 - RÉSULTATS EXPÉRIMENTAUX

Des attaches métalliques et céramiques, neuves et recyclées, ont été examinées à la fois sous faible grossissement (x3) et sous microscope atomique, ce dernier étant utilisé uniquement pour le fond de la gorge. Comme dans l'article auquel nous nous intéressons, une étude statistique a été réalisée.

Nous n'avons sélectionné que les attaches qui avaient été retenues pour ledit article, à savoir «Ormco Mini Diamond» et «American Orthodontics Master Series». Les photographies des attaches ont été prises à l'aide d'une caméra digitale Nikon Cool PIX 950 à travers un microscope

4 - EXPERIMENTAL EVIDENCE

Metallic and ceramic brackets, new and recycled, have been examined both under slight magnification (3X) and with the help of Atomic Force Microscopy (AFM), the latter being used only for the slot bottoms. As in the study we are answering to, no statistical examination was performed.

We have selected only these brackets which were examined in that article, i.e. Ormco Mini Diamond and American Orthodontics Master Series. The photographs of the brackets were taken with

stéréoscopique I.O.R. 200x. Celles des fonds de gorge ont été prises avec un Multimode Atomic Force Microscope mesurant la friction à travers ses possibilités d'examen latéral (Lateral Force Microscopy - LFM). Le système était raccordé à un «Nanoscope IIIa Controller» (Digital Instruments, Santa Barbara, CA). Les attaches examinées ont été prélevées dans notre échantillonnage de routine, soit destiné à la vente, soit au recyclage avant retour au client. Au lieu de les avoir jetées en les considérant comme endommagées, ce que nous faisons lors de nos procédures usuelles, nous les avons gardées pour justifier le point de vue selon lequel les marques d'attaches neuves actuelles ne peuvent pas être utilisées comme des modèles de référence, à suivre. Comme l'imagerie informatique permet aujourd'hui de faire des miracles et que ce que nous montrons peut apparaître incroyable, nous sommes impatients d'en adresser à tout laboratoire indépendant, pour confirmation des données.

Dans divers articles antérieurs, nous avons présenté d'autres types de marques qui ont été distribués sans une inspection correcte du fabricant¹⁹⁻²¹, mais également des marques sans examens comparatifs de fonds de gorge, à la fois pour des attaches métalliques et pour des attaches céramiques²⁵. Alors que les deux marques examinées nous semblèrent relativement acceptables du point de vue de leur susceptibilité à la corrosion²⁴, force est de constater qu'il y a sur le marché d'autres marques d'attaches neuves qui se dissolvent pratiquement en bouche, comme le montre la figure 1. Nous avons utilisé le terme : «relativement» parce que même dans le cas des attaches examinées dans cette étude, les Mini Diamond d'Ormco, il y avait une certaine dissolution de l'acier (avec des ions Ni et Cr que le patient absorbait). Cela était dû à la corrosion galvanique qui se produit à l'interface de l'attache acier / soudure or, comme l'expose la figure 2. En effet, se différenciant d'autres matériaux de soudure qui sont moins nobles que l'acier inoxydable, amenant l'attache à se détacher de sa base, dans le cas présent, c'est l'acier qui est solubilisé²³.

Le phénomène a été également décrit par d'autres observateurs¹⁵.

Un autre phénomène, en rapport avec celui-ci, phénomène qu'illustre la figure 3, est dû à la corrosion galvanique (différence dans la composition de l'acier de la grille) et à la réaction de

the help of a Nikon Cool Pix 950 digital camera through a stereoscopic microscope I.O.R. 200x. That of the slot bottoms were taken with a MultiMode Atomic Force Microscope measuring friction through its Lateral Force Microscopy (LFM) capability. The system was connected to a Nanoscope IIIa controller (Digital Instruments, Santa Barbara, CA). The brackets examined were taken from our routine examination of those offered for sale or to be recycled and returned. Instead of having them discarded as damaged, as in our usual procedure, we kept them to justify the point that today's brand new brackets cannot be considered as a standard to be followed. As computer imagery allows today to make wonders and what we will show may look incredible, we are eager to send them by request to any independent laboratory for data confirmation.

In several previous articles we have presented other types or brands which were released without the proper manufacturer inspection¹⁹⁻²¹ as well as comparative maps of slot bottoms, both metallic and ceramic²⁵. While both brands examined were found by us as relatively acceptable from the point of view of corrosion susceptibility²⁴, there are on the market other brand new brackets which practically dissolve in the mouth, as shown in fig. 1. We used the word "relatively" because even in the case of the brackets examined in this study, Ormco's Mini Diamond, there was some steel dissolution (with Ni and Cr ions leaching in the patient's body) due to the galvanic corrosion taking place at the interface gold brazing- steel bracket, as shown in fig. 2. Indeed, as a difference from other brazing materials which are less noble than stainless steel, leading to the detachment of the bracket from the base, this time the steel is the one which is solubilized²³.

The phenomenon has been described also by others¹⁵.

A related phenomenon, shown in fig. 3 is due both to galvanic corrosion

l'acier lorsqu'il est exposé à un écart de température impropre pendant la phase de laminage ou de traitement général, (réaction nommée par les Américains «sensitization»).

(difference in the steel compositions mesh-foil) and steel sensitization (exposure to an improper heat range during lamination or general processing).

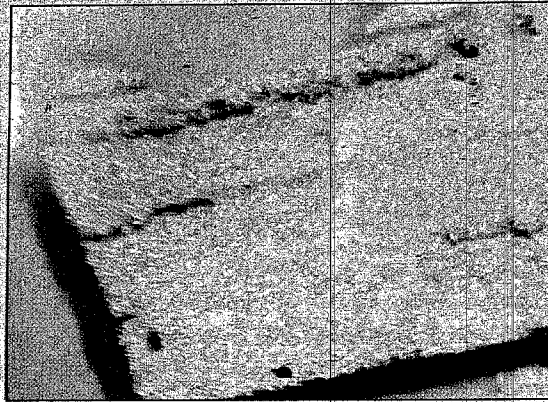


Figure 1

Base d'une attache, réalisée en acier inoxydable contenant du soufre, AISI 303 (S 30 300), gravement endommagée.

Heavily attacked base of an one-piece bracket made of the sulfur-containing stainless steel AISI 303 (S30300).



Figure 2

Attache Mini Diamond d'Ormco (MD) montrant une corrosion galvanique partielle au niveau de l'interface de la soudure.

Ormco Mini Diamond (MD) bracket exhibiting galvanic corrosion at the brazing interface.

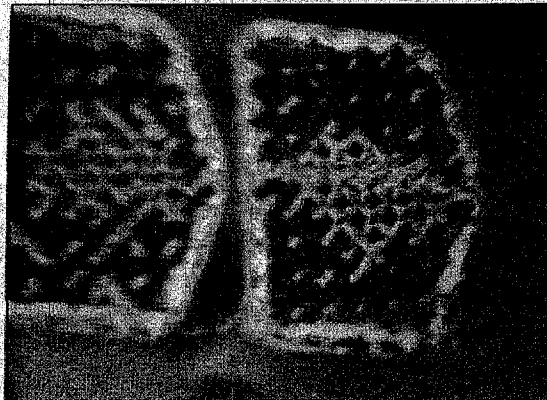


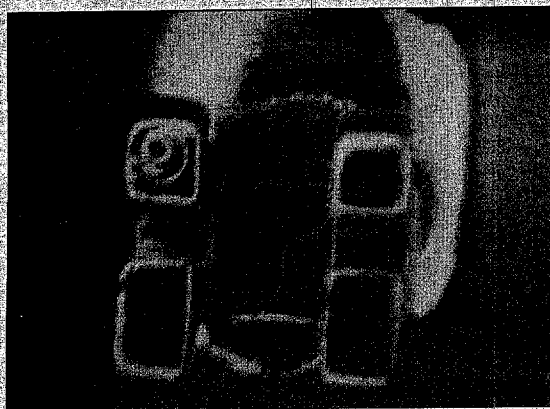
Figure 3

Attaches des American Orthodontic Master Series (MS) montrant un détachement partiel par corrosion de la grille.

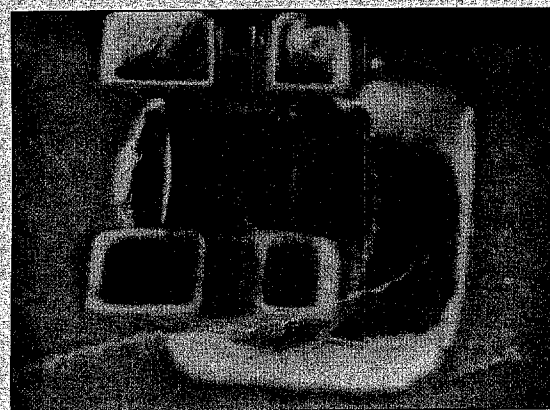
American Orthodontics Master Series (MS) brackets exhibiting partial corrosion/detachment of the mesh.

Les figures 4 à 10 illustrent l'ensemble de nos propos.

Figures 4 to 10 are illustrating the whole text.



a



b

Figures 4 a et / and b
Marquages incorrects sur des attaches MD.
Improper markings in MD brackets.

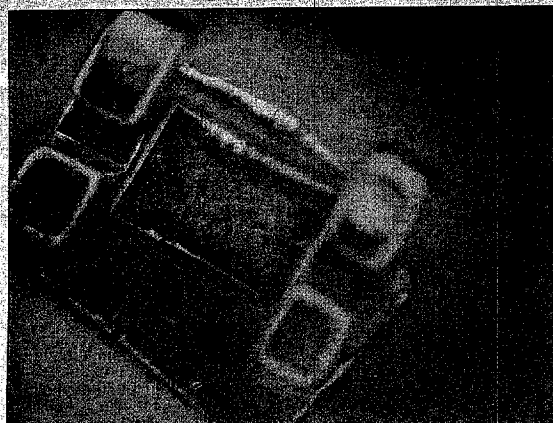
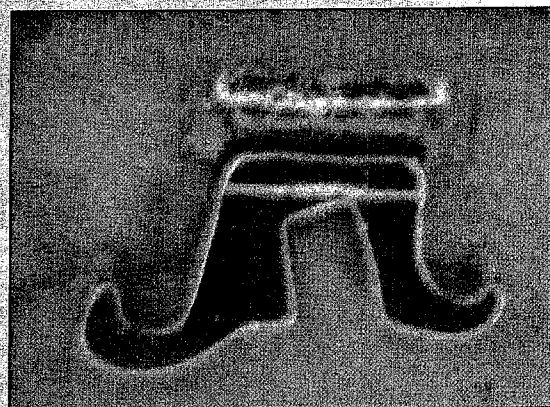


Figure 5
Angulation incorrecte d'une centrale (MD).
Improper angulation of a MD central.



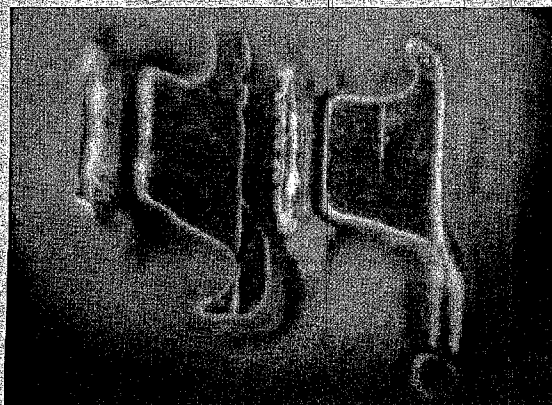
a



b

Figures 6 a et / and b
Torque inversé (vers le côté opposé à l'extension gingivale) de deux prémolaires, respectivement de la série MS et de la série MD. Un tel torque positif produit des dégâts dans le traitement...
Bracket with a reverse torque (opposing the gingival extension) of two bicuspids belonging to MS and MD, respectively. Such positive torque bring havoc with the treatment.

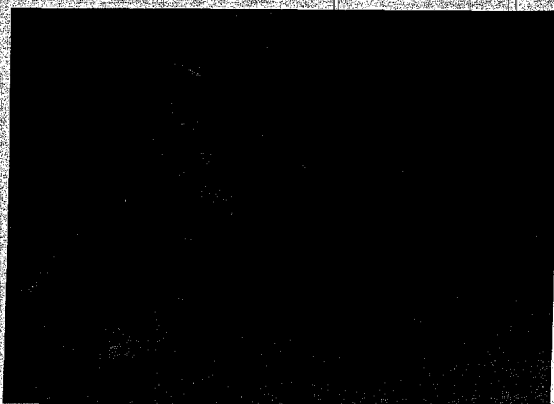
Attaches recyclées : doit-on considérer les attaches neuves comme des modèles de référence ?
Recycled brackets : should the new ones be considered a standard ?



Figures 7 et / and 8

Gorges insuffisamment entaillées, voire non entaillées du tout, respectivement dans des attaches canines MS et des attaches normales.

Bracket with insufficiently cut or even uncut slots in MS cuspids and MD centrals, respectively (see for the latter a comparison with a normal one).



a

Figures 9 a et / and 9b

b

Attaches provenant également des séries MD, où les gorges sont bouchées par de la soudure d'or.
Also from the MD series, brackets in where the slots are clogged with gold brazing.

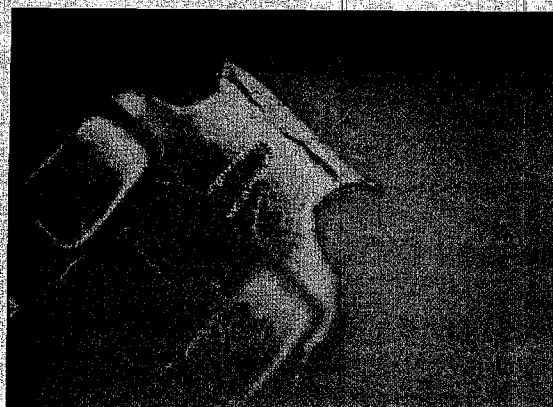


Figure 10

Attache dont la base est mal estampée.
Bracket with a poorly stamped base.

5 - DISCUSSION

Le simple examen des attaches que nous avons présentées démontre que des attaches neuves ne peuvent pas être prises pour des modèles de référence (de nos jours, il y a des milliers et des milliers d'attaches différentes, fabriquées par au moins 30 fabricants). Il est évident que les défauts relevés n'ont pu y être introduits que par leurs seuls fabricants. Aussi longtemps que ceci implique un contact humain pendant qu'elles ne sont soumises qu'à une inspection statistique, des attaches défectueuses continueront d'être livrées par les fabricants et par conséquent aux recycleurs. Si l'étude qui fait l'objet de cet article auquel nous répondons avait marqué chacune des attaches, l'examinant avant et après chaque reconditionnement pour s'assurer que les défauts observés avaient été réellement occasionnés par le recycleur, nous aurions tenté de répondre à chaque problème soulevé.

Loin de prétendre que le recycleur ne peut pas introduire sa propre marque, en soumettant les attaches de façon inappropriée à la chaleur ou à un électropolissage excessif ou en permettant à celles qui sont endommagées de passer au travers de l'inspection, il aurait été de bon aloi d'affirmer que son action est également bénéfique. En dehors du fait d'avoir abaissé les prix, la Ortho Cycle Co. a pendant des années (elle le fait toujours), non seulement rempli le rôle d'inspecteur final des attaches, mais en plus, elle a apporté une aide à certains fabricants, en électropolissant des attaches métalliques neuves ou en silanant des attaches céramiques.

Le fait que des attaches recyclées puissent être également supérieures aux neuves sous d'autres aspects que la seule inspection minutieuse de leur forme et de leur susceptibilité à la corrosion n'est pas assez connu. A cet égard, il est important de noter que la quantité de métaux lourds relâchés par des attaches neuves pendant le traitement initial est plus importante que celle des attaches de deuxième usage. En effet, la libération à la fois du nickel et du chrome atteint son maximum après deux semaines d'exposition; ensuite, le taux de libération diminue avec le temps¹. De même, le matériau de brasure le plus utilisé, un eutectique qui contient 20 % de nickel, libère au moins en partie ce métal nocif pendant le premier usage, le processus galva-

The simple examination of the brackets shown above demonstrates that new brackets (there are tens of thousands of different ones today, made by at least 30 manufacturers) cannot be taken as standards to be followed. It is obvious that the defects found couldn't have been introduced by any others than their manufacturer. As long as these will involve the human touch while being subjected only to a possible statistical inspection, faulty brackets will be continuously released by the manufacturers and subsequently by the recyclers. If the study we are responding to would have marked each bracket, examining it before and after reconditioning to make sure that the defects observed would have really been inflicted by the recycler, we would have tried to respond to each problem raised.

Far from claiming that the recycler cannot introduce his own imprint (by inappropriately subjecting the attachments to heat or excessive electropolishing or allowing the damaged ones to pass inspection), it would have also been fair to state that his action is also beneficial. Aside from keeping prices down, Ortho-Cycle Co. has worked for years (and is still doing it) not only as the attachments' final inspector, but even as a help for some manufacturers (by electropolishing at their requests new metallic attachments or by silanating ceramic ones).

Not enough known is the fact that recycled brackets can be superior to the new ones also in other respects than being thoroughly inspected both from the point of view of its shape and its corrosion susceptibility. In this respect, it is important to note that the amount of heavy metals released by new brackets during the initial treatment is higher than that of the ones which have already been subjected to it. Indeed, both the nickel and chromium release reach a maximum after two weeks of exposure, after which the rate of release diminishes with time¹. Likewise, the most used brazing material, an eutectic containing 20 % nickel, releases at least in part

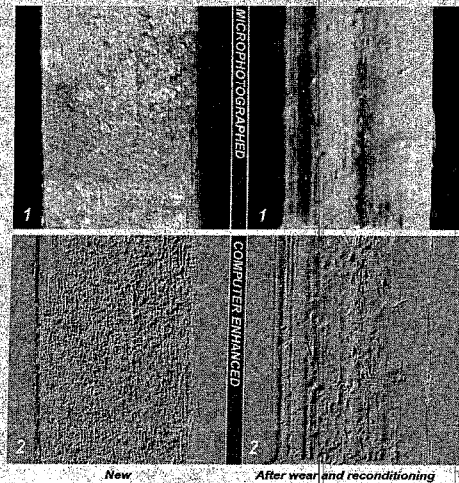


Figure 11

Ces attaches sont sans rapport avec les deux types examinés précédemment ; il s'agit ici d'une analyse sectionnelle de la base de deux attaches métalliques du même type, l'une neuve, l'autre recyclée²⁵. La surface lisse (moins de friction) est due à l'action de frottement de l'arc.

Unrelated to the two lines of brackets examined, the illustration shows the section analysis of the bottoms of two metallic brackets from the same line, one new and the other recycled²⁶. The smoothed surface (less friction) is due to the fretting action of the arch wire.

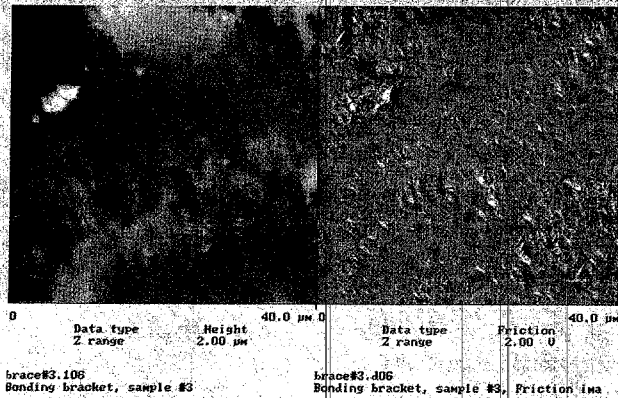


Figure 12

Le côté droit de cette figure montre l'aspect en microscopie de force latérale (Lateral Force Microscopy, LFM) de la gorge d'une attache céramique recyclée²⁵ ; les points noirs indiquent la présence de particules métalliques ayant encrassé les microfissures, ce qui contribue, avec l'enlèvement des aspérités, à rendre la surface plus lisse.

The right side of the figure shows the Lateral Force Microscopy (LFM) map of the slot of a recycled ceramic bracket²⁶; the darker spots indicate the presence of metal particles ingrained in the ceramic's microcracks which contribute, along the removal of the peaks, to render the surface smoother.

nique concerné étant connu comme une dissociation des constituants de l'alliage²³.

Il est évident que la gorge qui a été soumise à la friction de l'arc pendant deux ans sera plus lisse et présentera moins de friction qu'une attache neuve²⁵, comme le montre la figure 11. La même chose se produit avec les attaches céramiques, car neuves, elles opposent une friction plus élevée due aux aspérités dures du fond de la gorge, qui s'opposent au glissement de l'arc. Après avoir été usées pendant un certain temps, ces aspérités ont disparu et les creux ont été comblés par du métal provenant de l'arc. Ce nivellement se traduit par une friction moindre comme le montre la figure 12^{25, 26}.

Alors que les attaches métalliques peuvent être déposées sans se fracturer, les attaches céramiques présentent un plus grand risque de fracture, ce qui oblige le clinicien à enlever les restes à l'aide d'une fraise diamantée. Il est évident qu'une attache céramique qui a résisté sans

this harmful metal it during the first use, the galvanic process involved is known as dealloying²³. Second, it is obvious that the slot which has been subjected to fretting by the arch wire for two years will be smoother and offer less friction than a brand new one²⁵, as shown in fig. 11. The same happens also with the ceramic ones: while new, these offer the highest friction¹ due to the hard peaks of the slot bottom which are opposing the sliding of the arch wire. In contrast, after being worn for a while, these peaks are removed and the valleys are filled with metal from the wire. This levelling translates into a lower friction, as shown in fig. 12^{25, 26}.

While metallic brackets can be removed without breaking, the ceramic ones present a higher risk to fracture, circumstance in which the clinician is obliged to remove the rests with the help of a diamond burr.

dommages à la fois à l'usure et à une dépose, a moins de chances de se fracturer pendant le traitement qu'une attache neuve : comme les pierres précieuses, les attaches céramiques ont horreur des pores qui peuvent se comporter comme des points de concentration de stress pouvant mener à la fracture de l'attache.

It is obvious that a ceramic bracket which has withstood unscathed both wear and debonding will have less chances to break during the treatment than a new one : like gems, ceramic brackets hide pores which can act as stress concentration points leading to the attachments breakage.

6 - CONCLUSION

Les attaches recyclées ont été soumises à l'examen minutieux de la profession pendant plus d'un quart de siècle. La dernière enquête faite aux Etats-Unis (1990) a montré que 30 % des cliniciens ayant répondu au questionnaire réutilisent leurs attaches²⁶ ; au Royaume Uni¹⁷, leur nombre fut de 47,5 %. En nous basant sur notre propre expérience, nous pouvons affirmer que la propagande faite par les fabricants, qui est à l'origine de la discrétion de nos confrères, a provoqué une diminution du nombre des réponses de ceux qui réutilisent leurs attaches ; sans cette publicité, ce nombre eut été beaucoup plus important.

Nous pouvons aller plus loin, en affirmant que même ceux qui ne recyclent pas, sont intéressés par le recyclage, puisqu'ils ont des difficultés pour se débarrasser de leurs déchets médicaux, alors qu'ils peuvent percevoir jusqu'à 0,20 US \$ pièce en les vendant. Pour revenir à nouveau au problème, nous pensons que les années 2000 apporteront certainement du neuf, car maintenant, l'ensemble des praticiens se sera fait, d'une manière ou d'une autre, une opinion à ce sujet.

A notre connaissance, il y a quelques 30 fabricants d'attaches et à peu près autant de recycleurs²⁹, et peut-être même davantage, qui sont moins connus : ceci laisse de côté le nombre des cliniciens qui ont acquis leur propre système de recyclage, la «Big Jane», et reconditionnent à domicile. Comme avec les fabricants, certains des recycleurs sont en bas de l'échelle, alors qu'un petit nombre sont plus qu'en tête et se situent même plusieurs épaulés au-dessus. Comme dans toute activité humaine, certains ont abandonné, alors que d'autres prospèrent, en conformité avec leur acceptation par le public. De notre point de vue, condamner ceux qui recyclent des attaches et les blâmer pour des fautes commises en fait par les fabricants n'est pas seulement une injustice, mais encore une tentative de nuire au clinicien.

Recycled brackets have been under the orthodontic profession scrutiny for over a quarter of a century. The last survey made in the US (1990) has shown that over 30 % of the clinicians responding were reusing their attachments²⁶ in the United Kingdom¹⁷, their number in 1997 was 47,5 %. Based upon our experience, we can claim that, due to the propaganda exerted by the manufacturers which has forced them to discretion, their number should be considerably larger. We can go as far as to claim that even those who do not recycle, are interested in recycling, as they cannot only properly dispose of a medical waste, but also get as much as US\$ 0.20 a piece by selling them. To raise again the problem in the 2000's should really bring something new, as by now all the practitioners have made their mind about it, in a way or another.

There are some thirty brackets manufacturers and as many reconditioners²⁹, with perhaps many more who are less known: this leaves aside many clinicians who have purchased their own "Big Jane" reconditioning system and recycle these in house. As with the manufacturers, some of the recyclers are at the low end of the scale, while very few are more than head and shoulders above. As in any human activity, some have quit, while others prosper, in accordance with their acceptance by the public. In our view, to condemn those who recycle brackets and blame them for manufacturers' faults is not only an injustice, but also an attempt to harm the clinician.

Pour trouver des défauts dans nos attaches recyclées, l'étude qui a été faite dans l'article auquel nous nous intéressons se devait d'utiliser le microscope : en fait, pour détecter ces défauts dans des marques d'attaches neuves, l'œil nu suffit.

Au lieu de tenter de réfréner le recyclage et d'amener au silence ceux qui soulèvent des problèmes, les fabricants devraient améliorer leurs produits et réaliser des attaches moins chères et mieux sélectionnées. En dépit de leur succès actuel dans leur lutte contre la réutilisation de dispositifs médicaux, leur cause ne peut pas triompher dans un domaine où la technique a atteint de tels sommets. Nettoyer, décontaminer, inspecter et classer des éléments en acier inoxydable fait plus appel au sens des responsabilités qu'à l'adresse.

Tout ceci nous fait croire avec Victor Hugo : «qu'aucune armée ne peut vaincre une idée dont le temps est venu».

To find defects in our recycled brackets, the study we are responding had to use the microscope: to find these in the brand new ones, the unaided eye was enough.

Instead of trying to curb recycling and silencing those who raise problems, the manufacturers should improve their act and provide less expensive and better checked attachments. Irrespective of their present success in fighting the reuse of medical devices, their cause cannot triumph in an era when technology has reached such highs. To clean, decontaminate, inspect and sort stainless steel parts requires more responsibility than skill.

All this makes us believe that "No army can overcome an idea whose time has come" (Victor Hugo).

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Exhibit 2, Am. J. Orthod. 1993

LITIGATION AND LEGISLATION UPDATE

Litigation and legislation of particular interest to orthodontists will be reported under this section of the AMERICAN JOURNAL OF ORTHODONTICS AND DENTOFACIAL ORTHOPEDICS. Manuscripts for publication and readers' comments may be submitted to Ms. Sally A. Bowers, American Association of Orthodontists, 401 N. Lindbergh Blvd., St. Louis, MO 63141.

Recycled brackets

The Orthodontic Manufacturers Association's position on reconditioned brackets was published in the August and September 1992 issues of the AMERICAN JOURNAL OF ORTHODONTICS AND DENTOFACIAL ORTHOPEDICS.¹ On Oct. 2, 1992, Tom DiPasquale and I participated in a panel discussion on reuse and reconditioning of dental devices at the Fifth Annual Dentistry and the Law Conference. Following are some of the points I presented during that conference.

I believe that it is helpful to evaluate the issue of reuse of orthodontic brackets by analyzing the interests of the various parties involved. For simplicity sake, I have limited the discussion to what I believe are the four chief interested parties—firms that recondition, manufacturers of new brackets, patients, and orthodontists.

There are at least four firms that generate revenue from reconditioning orthodontic brackets. Therefore those firms have an economic interest in continuing the acceptance and use of reconditioned brackets. Beyond economic, they are also concerned with liability for any defective and/or dangerous products. One would assume that if their reconditioned devices did not work that their businesses would suffer and they would cease operation. Something must be working or these firms would not remain in business.

The manufacturers of new brackets also are profit motivated. They want to sell more new brackets. If the Food and Drug Administration (FDA) or some other governmental agency were to prohibit the use of reconditioned brackets, it is assumed that the manufacturers would sell more new brackets. They also have a products liability concern. If someone were to be injured by one of their brackets that was recycled, and if they could not prove that recycling took place or no other intervening cause for the injury, they could be found liable for any resulting injury.

As a side note, there are very few injuries from orthodontic appliances. In fact, I am unaware of any reported case dealing with orthodontic brackets. It is

possible that a bracket could become detached and the patient could swallow it. Those sort of mishaps, while rare, usually do not result in any injury to the patient.

Let's now evaluate the patient's viewpoint. What do patients expect? I would say high quality orthodontic treatment. Patients want safe, sterile treatment that is completed in a reasonable time period.

I suggest that you take an informal survey of your friends and relatives. How many would want their orthodontist to use recycled brackets on them or their children? Why? I did such a survey and found that no one wanted to have recycled brackets. I am guessing that the basis for the consumer's aversion to the reuse of dental devices is mostly an emotional or psychological reason. Given the choice, very few patients would want to have something placed in their mouth that had been in someone else's mouth, even if it has been properly sterilized.

The patients' interests could also be economic. However, we have no specific information about whether or not any cost savings when recycled brackets are used is being passed on to the patients. Maybe they are and we do not know about it. For example, maybe the practices that advertise very low prices are using recycled brackets. Also, maybe the use of recycled brackets has helped to keep the price down. We just do not have any data on this issue.

Given a consumer preference for new brackets, does the law require that patients be given information if the doctor plans to use recycled brackets? Neither the FDA rules nor policy guidelines nor other case laws specifically provide patients with the right of informed consent before the use of recycled brackets. The OMA article tried to persuade orthodontists that the legal theory of informed consent requires this disclosure, but I interpret informed consent differently. I believe that there is no precise or absolute standard regarding the quantum of information to be supplied to the patient. The fact is that doctors do not review with patients the various brand names of devices and drugs. They do not

discuss the pros and cons of each one and let the patients select what they want. Orthodontists do not explain to patients the various types of metal brackets on the market, the brand they prefer, and why. Selecting the product is part of the professional's responsibility and what the patients pay for when they buy professional services.

The law of informed consent only requires that foreseeable risks be explained to the patient. So before the patient has the legal right, due to informed consent, we must be aware that there are some risks to the patient when reconditioned brackets are used.

Could patients claim they were deceived by the use of recycled brackets and seek legal recourse under the legal theory of misrepresentation? Is the patient receiving less or something different than he was led to believe when he is treated with recycled brackets? Do recycled brackets have less value to the patient? Only if it could be shown that the particular recycled brackets used were defective, or less effective, in achieving satisfactory orthodontic results, could you have a case of misrepresentation. Most misrepresentation cases deal with consumer goods. For example, rolling back the odometer on a car and selling it as new. In those cases the purchasers thought they were getting a new car, and a new car has a greater value. I do not think the use of recycled brackets is analogous to the misrepresentation cases.

Lastly, let's look at the interests of the orthodontists and the AAO. Orthodontists also would have an economic interest. From the cost of the brackets standpoint, it is less expensive to use recycled brackets. One recycling firm claims that doctors save \$12,000 per year by recycling their brackets. If the doctor reconditioned the brackets himself in his own practice, the cost would be the staff's time.

However, in analyzing the economic motive, we should also look beyond the cost of the brackets and consider other economic factors. For example, the doctor's and staff's time is also an economic concern. If reused brackets result in more breakage, longer treatment time with more office visits, then the doctor could lose money by using recycled products. I would expect if this were the case, we would see very few dentists using recycled brackets.

Supposedly a number of practitioners use recycled brackets. The AAO has no information on the number of its members who use recycled brackets. The OMA article states that "many" orthodontists recycle brackets. The fact is, there is no reliable information on the precise number of practitioners who use recycled brackets on their patients. My thinking is that some of these high estimates include the practice of saving used brackets,

bands and wires, and selling them as scrap metal or selling them to reconditioners. Sometimes the "recycling" is a one way street out of the doctor's office and does not involve use of recycled brackets on their patients.

Another concern for orthodontists would be the legal costs. If the doctors are recycling their own brackets, then that intervening act, may make them liable for any faulty product and relieve the manufacturer from any products liability claim. In 1987 the FDA published its Compliance Policy Guidelines on Reuse of Medical Disposable Devices. Those guidelines specifically state that the practitioner who reuses a disposable medical device should be able to demonstrate: (1) sterilization; (2) that the physical characteristics or quality of the device will not be adversely affected; and (3) that the device remains safe and effective for its intended use. If dentists are recycling brackets in their own office or maintain ownership, then they bear the full responsibility for the safety and effectiveness of the devices.

From the scientific studies, it appears that the effects of recycling depends on (1) the type of recycling process and (2) the construction of the bracket: the type of steel from which the bracket is constructed, whether the bracket is milled or cast, and whether the bracket base is a mesh pad or a nonmesh, undercut integral pad. The most consistent finding is that recycling produces a reduction in bond strength, which is clinically insignificant.^{2,3}

Two textbooks used in orthodontic educational programs, *Contemporary Orthodontics*⁴ and *Orthodontics Current Principles and Techniques*,⁵ make reference to recycled brackets in their discussion on bracket removal. They note that metal brackets can be removed by either a special plier that grasps the edges of the base and breaks the attachment with a twisting motion or a cutter can be used to distort the bracket base, breaking the attachment. The first approach is more compatible with recycling of brackets, but the second approach is less likely to damage enamel. The texts note that the objectives of debonding are to remove the attachment and all the adhesive resin from the tooth and to restore the surface as closely as possible to its pretreatment condition without inducing iatrogenic damage. The more gentle technique of squeezing the bracket wings with pliers is more likely to destroy the brackets so they cannot be recycled. Also, the texts note that the more gentle technique is unlikely to cause damage to teeth. Therefore, when recycled brackets are used, there is not only a concern for the patient who is being treated with recycled brackets but also a concern for patients who suffer any injury or damage to their enamel during the debonding procedure. If the doctor

selects a debonding procedure that is more likely to injure the patient and the only reason that procedure was selected is because the doctor wants to reuse the brackets on another patient, the orthodontist could have some liability. It should be noted that I have not heard of any claims or reported cases due to the removal of metal brackets.

A prudent doctor who desires to use recycled products should carefully evaluate existing studies and constantly monitor new scientific studies. The doctor should be prepared to document the basis for his belief in the continued quality of the reused brackets. Also, the doctor should keep current on debonding techniques. The potential for patient discomfort and damage to tooth enamel should be considered when selecting the technique.

In any lawsuit against a doctor for negligence, the use of recycled brackets without the patient's knowledge could have a very damaging impact for the doctor's case. It is the sort of evidence that would make a jury sympathetic toward the patient. From a risk management point of view, the use of recycled brackets is riskier for the doctor and could have a negative impact in any malpractice case.

In researching the statutory, regulatory, case law and agency opinions on this issue I found that there is a lack of any information on reconditioned or recycled orthodontic brackets. In fact, there is very little information on reconditioning or reuse of any medical devices.

The FDA is charged with regulating all medical

devices. Given the fact that the failure of some devices have severe consequences, the death of or serious injury to the patient, the agency must first devote its resources to addressing those devices; for example, mechanical hearts and hemodialysis. Since brackets have not presented any harm to patients, they are not a priority for the FDA.

Finally, I would like to conclude with a note on what the role of the AAO has been in addressing this issue. The Board and Council on Practice Administration have been evaluating the issue for more than 3 years. The AAO and OMA have formed an Orthodontic Materials Committee and one of the committee's charges is to address material reuse. The AAO continues to encourage research projects aimed at establishing the properties for new and recycled brackets including strength dimensions and encourages manufacturers to submit products to the ADA's Acceptance Program.

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AAO MEETING CALENDAR

- 1993—Toronto, Canada, May 15 to 19, Metropolitan Toronto Convention Center
 1994—Orlando, Fla., May 1 to 4, Orange County Convention and Civic Center
 1995—San Francisco, Calif., May 12 to 17, Moscone Convention Center
 (*International Orthodontic Congress*)
 1996—Denver, Colo., May 12 to 16, Colorado Convention Center
 1997—Philadelphia, Pa., May 3 to 7, Philadelphia Convention Center
 1998—Dallas, Texas, May 16 to 20, Dallas Convention Center
 1999—San Diego, Calif., May 15 to 19, San Diego Convention Center

The AAO offers 1-800-STRAIGHT, an information/referral 800 telephone number, to consumers. Through this service, callers can request names of orthodontists in their area, information regarding free computer-imaged photographs, and general information brochures and literature on orthodontics. Approximately 12,000 calls are received annually. Recently, the Council on Communications authorized a study of this referral number to gauge its effectiveness and to determine consumers' use of the information.

The study found that the referral number does connect prospective clients with AAO members. Of those callers who received the list of orthodontists, 20.2 percent ultimately began treatment with an orthodontist, and 17.5 percent of the callers began treatment with an AAO orthodontist chosen from that list.

DATELINE ADDRESSES USE OF RECONDITIONED BRACKETS BY ORTHODONTISTS

On March 9, NBC Dateline reported on the use of reconditioned brackets by orthodontists. This news segment also appeared on MSNBC.

The report included an interview with AAO President Dr. Donald Poulton, who noted that these brackets are safe and effective. Due to AAO communications with its members, orthodontists were aware of Dateline's interest in this topic, as well as the date of the broadcast. Because of these communications, orthodontists were able to present the facts concerning reconditioned brackets to their patients.

Ultimately, the broadcast generated little consumer interest. The AAO received few calls from consumers following the broadcast.

1997 NATIONAL ORTHODONTIC HEALTH MONTH INCREASES PUBLIC AWARENESS OF BENEFITS OF ORTHODONTICS

Rolling out its third annual National Orthodontic Health Month program, the AAO introduced new artwork and resources for members that would allow them to promote the benefits of orthodontics in the media, their communities and offices during the month of October.

Artwork featuring a grinning, braces-wearing family of jack-o'-lanterns served as the centerpiece of the program. Members also received a flier that included a camera-ready article and camera-ready artwork, as well as promotional ideas, and two posters featuring the jack-o'-lantern artwork.

Orthodontic Residents Program (GORP) Aug. 8-10, 1997. The Ohio State University (OSU) hosted the event.

Residents had the opportunity to meet each other, as well as learn more about orthodontics. Each year, the AAO provides \$10,000 to help with the meeting's expenses.

1998 LEADERSHIP CONFERENCE DRAWS ACTIVE VOLUNTEERS IN THE AAO, CONSTITUENT AND COMPONENT ORGANIZATIONS AND PROMOTES GROUP DISCUSSIONS

Nearly 200 AAO members brought their ideas and input to the AAO Leadership Conference in January 1998.

Leadership and communication-building exercises, the plans to restructure the AAO, the AAO Strategic Plan, the AAO leadership structure, legislative issues, parliamentary procedure, marketing concepts and the Internet were all part of the agenda.

During this three-day conference in St. Louis, members had numerous opportunities to participate in round-table discussions and question-and-answer sessions. AAO staff members compiled the members' feedback on the restructuring issue and the AAO Strategic Plan.

AAO CONFERENCE HIGHLIGHTS THREE PRACTICE-RELATED TOPICS

More than 400 orthodontists, spouses and staff members attended the 1998 AAO Patient Care & Management and Practice Transition Conference in February. The speakers at this conference helped members tune up their practices in these three important areas. Marketing strategies, planning for practice transition, staff teamwork and customer service were all part of the three-day conference in Chicago.

This conference was part of the Council on Orthodontic Practice's continuing efforts to enhance orthodontists' practice management.

1998 ANNUAL SESSION TOPS OFF SUCCESSFUL YEAR

From the Opening Ceremonies to the lectures, Exhibit Hall and AAO House of Delegates, the 98th Annual Session, May 15-20, 1998, was a successful source of information, camaraderie and time of sharing for AAO members.

In all, 15,383 people attended the 98th Annual Session in Dallas. Nearly 35 percent of the AAO's practicing membership attended the meeting. In addition, orthodontists from 74 countries traveled to the United States to attend the Annual Session.

bers may participate in a credit card program designed specifically for them. To complement that service, MBNA, along with NOVA Information Systems Inc., is offering credit card processing services for orthodontic offices.

The AAO Board of Trustees has been reviewing affinity credit card programs and credit card processing services for more than a year. MBNA America is a Fortune 500 company and the world's leading issuer of the Gold MasterCard®. NOVA Information Systems Inc., the fifth largest credit card processor in the United States, has entered into a long-term marketing agreement to provide merchant processing services to MBNA customers.

Through the MBNA America credit card program, AAO members have access to credit cards that provide peerless benefits, service and convenience. Each card features the AAO logo, identifying cardholders as orthodontic professionals and committed members of the Association. The credit card processing program offers members a competitive rate for processing services.

AAO BOARD OF TRUSTEES APPROVES ENDORSEMENT OF ORTHODONTISTS FEE PLAN® FOR PATIENT FINANCING FOR ORTHODONTIC TREATMENT

During the 98th Annual Session, the AAO Board of Trustees voted to endorse Orthodontists Fee Plan® (OFP), a leading provider of patient financing for orthodontic treatment in the United States.

The Boards of the AAO and AAO Services Inc. have concluded, after a thorough evaluation, that OFP is a proven solution for enhancing the financial management of members' practices. The decision to endorse OFP recognizes its leadership role and the important value the program provides to members.

OFP has been serving the orthodontic community for more than five years. Major benefits can include increasing patient starts and revenue, reducing administrative costs, and creating a more financially efficient practice.



American Association of Orthodontists


Exhibit 3 Annual Report 1998

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